

REMARKS

Claims 1, 3, 10-13, 24, 25, and 27 are pending. Claims 2, 4-9, 14-23, 26, 28 and 29 have been cancelled. Applicants reserve the right to file one or more divisional applications directed to the subject matter of the non-elected claims.

The proposed amendments to the pending claims are made to more clearly define the inventions. It is submitted that the proposed amendments introduce no new matter and entry of the same is respectfully requested. By these amendments, the Applicants do not acquiesce to the propriety of any of the Examiner's rejections and do not disclaim any subject matter to which the Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

I. REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**A. Claims 1, 3, and 10-13 are rejected under 35 U.S.C. § 112, second paragraph**

The Examiner alleges that claims 1, 3, and 10-13 should be rejected under 35 U.S.C. § 112, second paragraph "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Paper No. 24 at page 2. Applicants respectfully traverse.

First, the Examiner alleges that claims 3 and 10 recite the limitation "said first hapten" and that "there is insufficient antecedent basis for this limitation in the claim." Paper No. 24 at page 3. Applicants submit proposed amendments to independent claim 1 and dependent claim 3, which recite to a "first non-HBV hapten." Therefore, Applicants submit that in view of the proposed amendments to the claims, sufficient antecedent basis exists. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejection of claims 3 and 10 under 35 U.S.C. § 112, second paragraph.

Next, the Examiner alleges that claim 11 recites the limitation "said second hapten" and that "there is insufficient antecedent basis for this limitation in the claim." Paper No. 24 at page 3. Applicants propose amendments to claims 3 and 11, which recite to a "second non-HBV hapten." Therefore, Applicants submit that there is sufficient antecedent basis in claim 11 for "a second non-HBV hapten." Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejection of claim 11 under 35 U.S.C. § 112, second paragraph.

Finally, the Examiner alleges that claims 12 and 13 are “vague and indefinite” because it is unclear whether the limitation of “at least one non-HBV hapten” in claim 1 is to be “considered as the “first” hapten, whether it is the same or different from the recited “first” in claims 12 and 13.” Paper No. 24 at page 3. Applicants submit that proposed amendments to claims 1 and 3, which recite to a “first non-HBV hapten” and “second non-HBV hapten,” respectively, and the proposed amendments to claims 12 and 13, more clearly define the claimed invention. Therefore, Applicants respectfully request reconsideration and withdrawal of the present rejection of claims 12 and 13 under 35 U.S.C. § 112, second paragraph.

II. REJECTION UNDER 35 U.S.C. § 102(b)

A. Claims 1, 3, 10-13, 24-25 and 27 are rejected under 35 U.S.C. § 102(b) anticipated by Birkett

The Examiner maintains that “claims 1, 3, 10-13, 24-25 and 27 remain rejected under 35 U.S.C. § 102(b) in view of Birkett.” Paper No. 24 at page 3. Applicants respectfully traverse.

Without addressing the propriety of the Examiner’s rejection, and specifically the Examiner’s interpretation of what the cited reference teaches or suggests, Applicants respectfully submit that the present rejection should be withdrawn because the Birkett patent is not prior art to the Applicants’ invention. The Birkett patent was based on an application filed on 12 February 1998 and issued on 15 May 2001. The Peterson Declaration and its associated evidence establish that the claimed invention was reduced to practice before 12 February 1998, the provisional filing date of the Birkett patent. Referring to the Peterson Declaration, Dr. Peterson attests that he is the inventor of the above-identified patent application. ¶1. Furthermore, he has read and is familiar with the Final Office Action mailed 10 March 2003 in this application. ¶2. Dr. Peterson understands that in the Final Office Action mailed 10 March 2003, the Examiner rejected claims 1, 3, 10-13, 24-25 and 27 as anticipated in view of the Birkett patent. ¶3. Dr. Peterson has read and is familiar with the Birkett patent and understands that the patent was provisionally filed on 12 February 1998 and issued on 15 May 2001. ¶4.

Dr. Peterson has provided a copy of his laboratory notebook pages, prepared by Jian Zheng under his supervision. ¶5. Page 41 of the laboratory notebook, attached to the

Peterson Declaration as Exhibit B, evidences that Dr. Peterson, as the inventor of the subject matter claimed and disclosed in the present application, reduced to practice, *inter alia*, the inventions of the instant application.

Specifically, the laboratory notebook at *e.g.*, page 41, summarizes and evidences the reduction to practice of the present invention. In particular, page 41 presents a protein gel in which genetically altered duck hepatitis B nucleocapsid particles were denatured and run on a gel to confirm the insertion of a non-HBV antigen (malarial antigen CSII) into the amino acid sequence of the nucleocapsid monomer. ¶6. The experimental data summarized on these pages was collected and memorialized in this notebook before 12 February 1998, the provisional filing date of the Birkett Patent. *Id.* Page 43 (date redacted) of the same laboratory notebook evidences that the experiment summarized on page 41 was performed before 12 February 1998. *Id.* In addition, this work was performed in the United States. *Id.* Accordingly, the Birkett patent does not constitute prior art due to Applicants' reduction to practice of the present invention before the provisional filing date of the Birkett patent.

Therefore, in view of the Peterson Declaration, Applicants submit that the Birkett patent is not prior art to the Applicants' invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejection.

III. CONCLUSION

Applicant has properly and fully addressed each of the Examiner's grounds for rejection. Applicant submits that the present application is now in condition for allowance. If the Examiner has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited.

If there are any additional fees due in connection with the filing of this amendment, please charge the fees to undersigned's Deposit Account No. 50-1067. If any extensions or fees are not accounted for, such extension is requested and the associated fee should be charged to our deposit account.

Respectfully submitted,

5 September 2003



Don J. Peltz
Reg. No. 33,754

Preston Gates Ellis & Rouvelas Meeds, L.L.P.
1735 New York Ave., NW, Suite 500
Washington, DC 20006
Telephone: (202) 628-1700
Facsimile: (202) 331-1024



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. 09/495,947 Confirmation No. 5493
Applicant Timothy Coleman *et al.*
Filed 2 February 2000
TC/Art Unit 1632
Examiner Q.J. Li

Docket No. 48507-00002
Customer No. 23767

For: ADVANCED ANTIGEN PRESENTATION PLATFORM

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SEP 09 2003
TECH CENTER 1600/2900

DECLARATION OF DARRELL PETERSON, Ph.D. UNDER 37 CFR § 1.131

Mail Stop AF
Commissioner for Patents
Alexandria, VA 22313-1450

I, Darrell Peterson, Ph.D., declare the following:

1. I am the inventor of the above-identified patent application, Serial No. 09/495,947.

2. I have read and I am familiar with the Final Office Action mailed 10 March 2003 pertaining to this application.

3. I understand that in the Final Office Action mailed 10 March 2003 the Examiner rejected claims 1, 3, 10-13, 24-25 and 27 as anticipated in view of Birkett, U.S. Patent No. 6,231,864 B1 ("Birkett"). A copy of the Birkett patent is attached as Exhibit A.

4. I have read and I am familiar with Birkett. It is my understanding that the Birkett patent was filed provisionally on 12 February 1998 and issued on 15 May 2001.

5. Attached as Exhibit B is a copy of the relevant pages from a laboratory notebook prepared by Jian Zheng under my supervision. The notebook pages evidence that I, as the inventor of the subject matter claimed and disclosed in the present application, reduced to practice, *inter alia*, the inventions that are disclosed and claimed in the present application Serial No.09/495,947.

6. Notebook page 41 summarizes and evidences the reduction to practice of the inventions in the present application Serial No. 09/495,947. The experimental data summarized on these pages, evidencing the reduction to practice of the claimed inventions, was performed before 12 February 1998. Specifically, the laboratory notebook page shows a gel in which genetically altered duck hepatitis B nucleocapsid particles were denatured and run on a gel to confirm the insertion of a non-HBV antigen (malarial antigen CSII) into the amino acid sequence of the nucleocapsid monomer. Page 41 is the recorded entry of the production of this modified duck hepatitis B protein monomer, denatured from its particulate state, as shown by the protein gel. Page 43 (date redacted) of the same laboratory notebook evidences that the experiment summarized on page 41 was performed before 12 February 1998. In addition, this work was performed in the United States.

7. All statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and such willful false statements may jeopardize the validity of the application or any patents issuing thereon.


Inventor: Darrell Peterson, Ph.D.

Date 3 Sep 03

PROJECT Green Duck (ST (Tie))

Notebook No. _____

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2:10 AM Type. 2 1/2 hours Name / Keen 7-18 value \$500
Realtor - real estate agent ADP 40

Get ~ 200 sq. ft. land good in S.E.
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I am the owner of the property
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Read and Understood By

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Date

PROJECT Rule File E a File Card

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